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**PATENT APPLICATION
TRANSMITTAL LETTER**

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2600/47701

Address to:
Assistant Commissioner for Patents
Washington D.C. 20231
Box Patent Application

Transmitted herewith for filing is the patent application of

Inventor(s): **Kobi RICHTER**

For : **APPARATUS AND METHOD FOR SELECTIVELY POSITIONING A
DEVICE AND MANIPULATING IT**

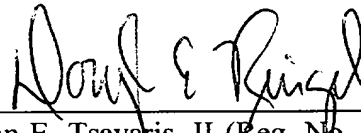
Enclosed are:

1. 12 sheets of specification, 7 sheet of claims, and 1 sheet of abstract.
2. 6 sheet(s) of drawings.
3. Declaration and Power of Attorney (unsigned).
4. The filing fee has been calculated as shown below:

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BASIC FEE				790.00
TOTAL CLAIMS	13 - 20 =	0	22.00	0.00
INDEPENDENT CLAIMS	7 - 3 =	4	82.00	328.00
MULTIPLE DEPENDENT CLAIM PRESENT			270.00	
*Number extra must be zero or larger			TOTAL	1,118.00
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Dated: 31 July 1998

By:  #34,416, for
John E. Tsavaris, II (Reg. No. 33,804)

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TYPE OF DOCUMENT Patent Application for Kobi Richter

"APPARATUS AND METHOD FOR SELECTIVELY POSITIONING
A DEVICE AND MANIPULATING IT"

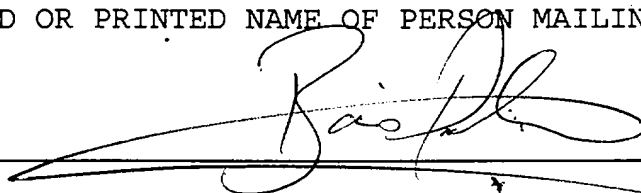
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1 APPARATUS AND METHOD FOR SELECTIVELY POSITIONING A DEVICE AND
2 MANIPULATING IT

3
4 FIELD OF THE INVENTION

5 This invention relates generally to an apparatus and
6 method of selectively positioning the apparatus, e.g., within a
7 lumen. More particularly, this invention relates to a device and
8 method for pulling a catheter along a wire; a device and method
9 for moving a wire relative to a catheter, a device and method for
10 pulling a catheter relative to a guiding catheter or any larger
11 bore pipeline through which it is inserted; and a device and
12 method for pushing or pulling a device on top of a guide wire or
13 inside a guiding catheter.

14
15 BACKGROUND OF THE INVENTION

16 In many different applications of invasive and
17 minimally invasive medicine there is a need to introduce
18 catheters and other devices into the body, usually through open
19 lumens or closed lumens, utilizing percutaneous entry.
20 Conventional procedures for the introduction of the devices and
21 their controlled motion in the body usually utilize a force,
22 either a manual force or a motorized force, applied from the
23 outside of the patient to "push" the device to the target area.
24 One shortcoming of introducing the device via a "push" operation,
25 even when done on top of a guiding wire, is that this procedure
26 often does not provide optimal tractability into a tortuous
27 anatomy, e.g., the coronary arteries. In contrast, a "pull"

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1 operation in which a pulling device precedes the apparatus and
2 "pulls" it into place increases the tractability of the device
3 and reduces the likelihood that the device will get caught in a
4 curve of the lumen or cause trauma to the lumen.

5 Another problem is the need to push wires through
6 occluded lumen sections that have a great resistance to such
7 penetration. The fact that the wire is pushed from the outside
8 may waste all the pushing energy in accessive loops with very
9 little or none of the pushing energy actually reaching the tip of
10 the wire.

11 12 OBJECTS AND SUMMARY OF THE INVENTION

13 It is an object of this invention to provide a device
14 and method for pulling a catheter along a wire.

15 It is another object of this invention to provide a
16 device and method for pushing a wire relative to a catheter.

17 In yet another object of this invention to provide a
18 device and method for pulling a catheter relative to a guiding
19 catheter or any larger bore pipeline through which it is
20 inserted.

21 It is a further object of this invention to provide a
22 device and method for pushing or pulling a device on top of a
23 guidewire or inside a guiding catheter.

24 It is still a further object of this invention to
25 provide an apparatus and method for selectively positioning a
26 device, e.g., a stent, an Intra Vascular Sound (IVUS) transducer,

an atherectomy device (both rotational and directional), pressure sensors, balloons, and pushing wires to open occlusions, by pulling rather than pushing these devices into place.

It is an object of this invention to provide an apparatus for disposing a device in the target area of a lumen, comprising: a cylindrically shaped motor attached to the device, the motor having a longitudinal bore, the motor provided with a motor friction area disposed within the longitudinal bore; a guide wire disposed within the longitudinal bore, the guide wire and the longitudinal bore sized and adapted to impart friction between the friction area of the motor and the guide wire in an amount sufficient to permit the motor to change position relative to the guide wire by crawling against the guide wire when the motor is energized.

It is another object of this invention to provide an apparatus for disposing a device in the target area of a lumen, comprising: a cylindrically shaped motor attached to the device, the motor having an outer surface, the motor provided with a friction area on the outer surface; a cylindrical guide tube having an outer surface and an inner surface defining a longitudinal bore, the outer surface of the motor and the inner surface of the guide tube sized and adapted to impart friction between the friction area of the motor and the inner surface of the cylindrical guide tube in an amount sufficient to permit the cylindrical motor to change position relative to the guide tube by crawling against the inner surface of the guide tube when the

motor is energized.

It is still another object of this invention to provide an apparatus for disposing a stent in the target area of a lumen, comprising: a catheter having a proximal end, a distal end, a longitudinal bore therethrough, and an expandable balloon disposed at the distal end; a cylindrically shaped motor disposed at the distal end of the catheter distal to the balloon, the motor having a longitudinal bore communicating with the longitudinal bore of the catheter, the motor provided with a motor friction area disposed within the longitudinal bore; a guide wire disposed within the longitudinal bore of the catheter and the longitudinal bore of the motor, the guide wire and the longitudinal bore of the motor sized and adapted to impart friction between the friction area of the motor and the guide wire in an amount sufficient to permit the motor to change position relative to the guide wire by crawling against the guide wire when the motor is energized.

It is another object of this invention to provide a method of disposing a stent in the target area of a lumen, comprising the steps of:

a) constructing an apparatus comprising: a catheter having a proximal end, a distal end, a longitudinal bore therethrough, and an expandable balloon disposed at the distal end; a cylindrically shaped motor disposed at the distal end of the catheter distal to the balloon, the motor having a longitudinal bore communicating with the longitudinal bore of the catheter,

the motor provided with a motor friction area disposed within the longitudinal bore, a guide wire disposed within the longitudinal bore of the catheter and the longitudinal bore of the motor, the guide wire and the longitudinal bore of the motor sized and adapted to impart friction between the friction area of the motor and the guide wire in an amount sufficient to permit the motor to change position relative to the guide wire by crawling against the guide wire when the motor is energized;

- b) advancing the guide wire to the target area;
- c) securing the guide wire;
- d) energizing the motor so that it advances along the guide wire to the target area to dispose the stent in the target area of lumen;
- e) inflating the balloon to secure the stent in the target area of the lumen;
- f) deflating the balloon; and
- g) withdrawing the guide wire, motor, and catheter from the lumen.

It is yet another object of this invention to provide a method of disposing a stent in an obstructed target area of a lumen, comprising the steps of:

- a) constructing an apparatus comprising: a catheter having a proximal end, a distal end, a longitudinal bore therethrough, and an expandable balloon disposed at the distal end; a cylindrically shaped motor disposed at the distal end of the catheter distal to the balloon, the motor having a

longitudinal bore communicating with the longitudinal bore of the catheter, the motor provided with a motor friction area disposed within the longitudinal bore, a guide wire disposed within the longitudinal bore of the catheter and the longitudinal bore of the motor, the guide wire and the longitudinal bore of the motor sized and adapted to impart friction between the friction area of the motor and the guide wire in an amount sufficient to permit the motor to change position relative to the guide wire by crawling against the guide wire when the motor is energized;

- b) advancing the guide wire to the target area;
- c) securing the guide wire;
- d) energizing the motor so that the motor advances along the guide wire to the obstructed target area;
- e) securing the catheter;
- f) energizing the motor so that the guide wire advances through the longitudinal bore of the motor and into the obstructed target area of the lumen;
- g) securing the guide wire;
- h) energizing the motor so that the motor advances along the guide wire and disposes the stent in the target area of the lumen;
- i) inflating the balloon to secure the stent in the target area of the lumen;
- j) deflating the balloon; and
- k) withdrawing the guide wire, motor, and catheter from the lumen.

1
2
3 BRIEF DESCRIPTION OF THE DRAWINGS

4 FIG. 1 shows an embodiment of the invention in which a
5 cylindrically shaped motor and a guide wire are utilized to
6 dispose a device in the target area of a lumen;

7 FIG. 2 is a cross-sectional end view of the embodiment
8 of the invention shown in FIG. 1;

9 FIG. 3 shows an embodiment of the invention in which a
10 cylindrical motor and a cylindrical guide tube are used to
11 dispose a device in the target area of a lumen;

12 FIG. 4 shows a cross-sectional side view of another
13 embodiment of the invention shown in FIG. 3;

14 FIG. 5 shows the tractability of a catheter that is
15 pulled through a curve in a lumen in accordance with the present
16 invention;

17 FIG. 6 shows the tractability of a catheter that is
18 pushed through a curve in a lumen in a conventional manner;

19 FIG. 7 shows an embodiment of the invention used to
20 dispose a balloon expandable stent in the lumen of a blood
21 vessel;

22 FIGS. 8A to 8D shows an embodiment of the invention
23 used to clear an obstructed lumen; and

24 FIG. 9 shows an alternative embodiment of the
25 invention.
26

1
2 DETAILED DESCRIPTION OF THE INVENTION

3 Miniature Oscillating Ceramic Motors (OCM) are well
4 known in the art and are disclosed in U.S. patent 5,453,653 to
5 Zumeris the specification of which is incorporated herein by
6 reference. These motors can be made very small and in any shape
7 and they operate by contacting a surface in an amount sufficient
8 to generate sufficient friction to permit the motor to "crawl"
9 along the contacted surface and change its position relative to
10 the contacted surface when the motor is energized. These motors
11 can be adequately insulated to act in aqueous environments.
12 Their small size and low energy level requirements make them
13 especially suitable for use inside living organisms.

14 FIG. 1 is a lateral perspective of one embodiment of
15 the invention and shows a cylindrical motor 1 having a
16 longitudinal bore therethrough. A guide wire 2 is disposed
17 within the longitudinal bore 5. FIG. 2 is a cross-sectional end
18 view taken on line A-A of FIG. 1 and shows the cylindrical motor
19 1 having an outer surface 3 and an inner surface 4 defining a
20 longitudinal bore 5. The inner surface 4 defining the
21 longitudinal bore 5 is provided with a friction area 6 adapted to
22 engage the guide wire 2. The longitudinal bore 5 and the guide
23 wire 2 are sized and adapted so that when the motor 1 is
24 energized the motor 1 will crawl along the guide wire 2, thus,
25 changing its position relative to the guide wire 2. The
26 direction of movement is controlled selectively by energizing

wires (not shown) connected to the motor 1. In one embodiment, shown in FIG. 2, a biasing means, e.g., a leaf spring 7 is utilized to bias the guide wire 2 against the friction area 6 of the motor 1.

FIG. 3 is a cross-sectional side view of another embodiment of the invention and shows a cylindrical motor 8 having an external surface 10 mounted within a guide tube 9 having an outer surface 11 and an inner surface 12. The external surface 10 of the motor 8 and the internal surface 12 of the guide tube 9 are sized and adapted so that the friction area 14 of the motor 8 contacts the inner surface 12 of the guide tube 9 and crawls along the inner surface 12 so as to dispose a device, e.g., an Intra Vascular Ultra Sound (IVUS) transducer, atherectomy device, or physiological sensor, (not shown) in the target area of a lumen. In an especially preferred embodiment, shown in FIG. 4, a leaf spring 13 is utilized to bias the friction surface 14 of the motor 8 against the internal surface 12 of the guide tube 9.

In another embodiment of this invention, shown in FIG. 7, a balloon catheter with a micro-motor disposed at the distal end is used to dispose an expandable stent in the target area of a lumen. FIG. 7 shows a catheter 15 having a proximal end 16, a distal end 17, and a longitudinal bore 18 therethrough. An expandable balloon 19 is disposed at the distal end 17. A cylindrically shaped motor 1 is disposed at the distal end 17 of the catheter 15 distal to the balloon 19. The motor 1 has a

1 longitudinal bore 5 communicating with the longitudinal bore 18
2 of the catheter 15 and is provided with a motor friction area 6
3 disposed within the longitudinal bore 5 of the motor 1. A guide
4 wire 2 is disposed within the longitudinal bore 18 of the
5 catheter 15 and the longitudinal bore 5 of the motor 1. The
6 guide wire 2 and the longitudinal bore 5 of the motor 1 are sized
7 and adapted to impart friction between the friction area 6 of the
8 motor 1 and the guide wire 2 in an amount sufficient to permit
9 the motor 1 to change position relative to the guide wire 2 by
10 crawling against the guide wire 2 when the motor 1 is energized.

11 In operation, an expandable stent 20 is secured to the
12 balloon portion 19 of the catheter 15 and the guide wire 2 is
13 placed into the bore 18 of the catheter 15. The guide wire 2 is
14 then introduced into the lumen to be treated and is advanced by
15 pushing it until it is near the target area. The guide wire 2 is
16 then secured. The micro-motor 1 is then energized so that it
17 crawls along the guide wire 2 which pulls the catheter 15 into
18 the proximity of the target area to be treated. Because the
19 catheter 15 is "pulled" into position as shown in FIG. 5, there
20 is improved tractability and less kinking of the catheter 15,
21 and, thus, reduced risk of trauma to the internal surface of the
22 lumen than when the catheter is "pushed" into place using
23 conventional procedures as shown in FIG. 6. The balloon 19 is
24 then expanded to secure the stent 20 in the target area of the
25 lumen. The balloon 19 is then deflated and the guide wire 2 and
26 the catheter 15 are pulled out of the lumen using conventional

1 methods.

2 In another embodiment of this invention shown in FIGS.
3 8A to 8D, the motor is used to push the guide wire into, and if
4 specific applications dictate through, a constricted area which
5 clears the vessel of the obstruction to permit the catheter to
6 advance beyond the obstruction to the target area. In operation,
7 the catheter 15 is mounted on a guide wire 2 as previously
8 discussed. The guide wire 2 is advanced to the obstruction 21 as
9 shown in FIG. 8A. The guide wire 2 is secured and the motor is
10 energized causing the catheter to advance towards the obstruction
11 21. The catheter 15 is advanced until it too is in proximity to
12 the obstruction 21 as shown in FIG. 8B. The catheter 15 is then
13 secured and the motor 1 is activated which causes the guide wire
14 2 to advance into the obstructed area 21 as shown in FIG. 8C. In
15 some applications, one or more passes may be utilized to clear
16 the obstruction 21. The guide wire 2 is then secured, the motor
17 1 is energized, and the catheter 15 is advanced through the
18 vessel past the area from which the guide wire 2 has cleared the
19 obstruction 21 from the target area as shown in FIG. 8D. This
20 method may be used to simply clear an obstruction in a lumen as
21 discussed above or may be used in conjunction with other
22 embodiments of the invention, e.g., to facilitate the placement
23 of an expandable stent in the target area of a lumen by first
24 clearing the target area of any obstructions.

25 FIG. 9 shows an alternative embodiment of the invention
26 and shows a slab-shaped motor 22 incorporated in a catheter 23.

1 In the embodiment shown in FIG. 9, the motor 22 is shaped like a
2 slab instead of being cylindrical. The slab-shaped motor 22 is
3 disposed on the inner wall of the catheter 23 and is provided
4 with a friction area 6 sized and adapted to frictionally engage a
5 guide-wire 2. The slab-shaped motor 22 is sized and adapted to
6 permit the catheter 23 to be moved relative to the guide-wire 2
7 as previously discussed and as shown in FIG. 9.

8 While the invention has been described with respect to
9 a limited number of embodiments, it will be appreciated that many
10 variations, modifications, and other applications of the
11 invention may be made.

WHAT IS CLAIMED IS:

1. An apparatus for disposing a device in the target area of a lumen, comprising: a cylindrically shaped motor attached to said device, said motor having a longitudinal bore, said motor provided with a motor friction area disposed within said longitudinal bore; a guide wire disposed within said longitudinal bore, said guide wire and said longitudinal bore sized and adapted to impart friction between said friction area of said motor and said guide wire in an amount sufficient to permit said motor to change position relative to said guide wire by crawling against said guide wire when said motor is energized.

2. The apparatus of claim 1, further comprising a biasing means to bias said guide wire against said friction area.

3. The apparatus of claim 2, wherein said biasing means is a leaf spring.

4. An apparatus for disposing a device in the target area of a lumen, comprising: a cylindrically shaped motor attached to said device, said motor having an outer surface, said motor provided with a friction area on said outer surface; a cylindrical guide tube having an outer surface and an inner surface defining a longitudinal bore, said outer surface of said motor and said inner surface of said guide tube sized and adapted

to impart friction between said friction area of said motor and said inner surface of said cylindrical guide tube in an amount sufficient to permit said cylindrical motor to change position relative to said guide tube by crawling against said inner surface of said guide tube when said motor is energized.

5. The apparatus of claim 4, further comprising a biasing means to bias said inner surface of said guide tube against said friction area.

6. The apparatus of claim 5, wherein said biasing means is a leaf spring.

7. A method of disposing a device in the target area of a lumen, comprising the steps of:

a) constructing an apparatus comprising a cylindrically shaped motor attached to said device, said motor having a longitudinal bore, said motor provided with a motor friction area disposed within said longitudinal bore, a guide wire disposed within said longitudinal bore, said guide wire and said longitudinal bore of said motor sized and adapted to impart friction between said friction area of said motor and said guide wire in an amount sufficient to permit said motor to change position relative to said guide wire by crawling against said guide wire when said motor is energized;

b) advancing said guide wire to said target area;

- c) securing said guide wire;
- d) energizing said motor so that said motor advances along said guide wire to said target area to dispose said device in said target area of said lumen; and
- e) withdrawing said guide wire, motor, and device from said lumen.

8. A method for disposing a device in the target area of a lumen, comprising the steps of:

- a) constructing an apparatus comprising: a cylindrically shaped motor having an outer surface, said motor provided with a friction area on said outer surface, a cylindrical guide tube having an outer surface and an inner surface defining a longitudinal bore, said outer surface of said motor and said inner surface of said guide tube sized and adapted to impart friction between said friction area and said inner surface of said cylindrical guide tube in an amount sufficient to permit said cylindrical motor to change position relative to said guide tube by crawling against said inner surface of said guide tube when said motor is energized;
- b) advancing said guide tube to said target area;
- c) securing said guide tube;
- d) inserting said motor attached to said device in said bore of said guide tube;
- e) energizing said motor so that said motor advances along said inner surface of said guide tube to said target area to

dispose said device in said target area of said lumen; and

f) withdrawing said guide tube, motor, and device from said lumen.

9. An apparatus for disposing a stent in the target area of a lumen, comprising: a catheter having a proximal end, a distal end, a longitudinal bore therethrough, and an expandable balloon disposed at said distal end; a cylindrically shaped motor disposed at said distal end of said catheter distal to said balloon, said motor having a longitudinal bore communicating with said longitudinal bore of said catheter, said motor provided with a motor friction area disposed within said longitudinal bore of said motor; a guide wire disposed within said longitudinal bore of said catheter and said longitudinal bore of said motor, said guide wire and said longitudinal bore of said motor sized and adapted to impart friction between said friction area of said motor and said guide wire in an amount sufficient to permit said motor to change position relative to said guide wire by crawling against said guide wire when said motor is energized.

10. The apparatus of claim 9, further comprising a biasing means to bias said guide wire against said friction area.

11. The apparatus of claim 10, wherein said biasing means is a leaf spring.

12. A method of disposing a stent in the target area of a lumen, comprising the steps of:

a) constructing an apparatus comprising: a catheter having a proximal end, a distal end, a longitudinal bore therethrough, and an expandable balloon disposed at said distal end; a cylindrically shaped motor disposed at said distal end of said catheter distal to said balloon, said motor having a longitudinal bore communicating with said longitudinal bore of said catheter, said motor provided with a motor friction area disposed within said longitudinal bore of said motor, a guide wire disposed within said longitudinal bore of said catheter and said longitudinal bore of said motor, said guide wire and said longitudinal bore of said motor sized and adapted to impart friction between said friction area of said motor and said guide wire in an amount sufficient to permit said motor to change position relative to said guide wire by crawling against said guide wire when said motor is energized;

b) advancing said guide wire to said target area;

c) securing said guide wire;

d) energizing said motor so that it advances along said guide wire to said target area to dispose said stent in said target area of said lumen;

e) inflating said balloon to secure said stent in said target area of said lumen;

f) deflating the balloon; and

g) withdrawing said guide wire, motor, and catheter from

- g) securing said guide wire;
- h) energizing said motor so that said motor advances along said guide wire and disposes said stent in said target area of said lumen;
- i) inflating said balloon to secure said stent in said target area of said lumen;
- j) deflating said balloon; and
- k) withdrawing said guide wire, motor, and catheter from said lumen.

ABSTRACT

Apparatus for pulling and positioning an apparatus, e.g., a stent, in the target area of a lumen. In one embodiment, a cylindrically shaped motor has a longitudinal bore, a friction area within the longitudinal bore, and a guide wire disposed within the longitudinal bore. The guide wire and friction area of the motor are sized and adapted to contact each other and impart friction between the friction area and the guide wire to permit the motor to pull a catheter to the target area by crawling against the guide wire. In another embodiment, a cylindrical motor having a friction area on its outer surface is disposed within a guide tube.

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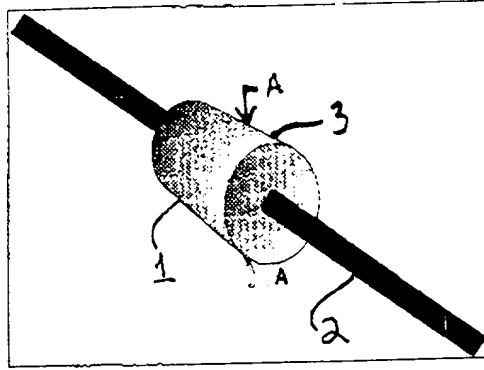


FIG. 1

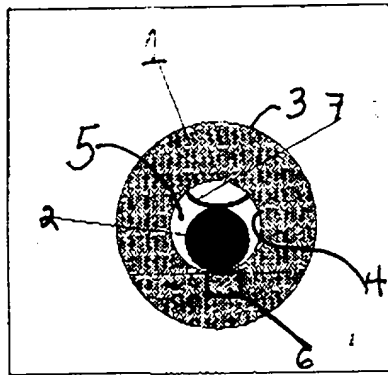


FIG. 2

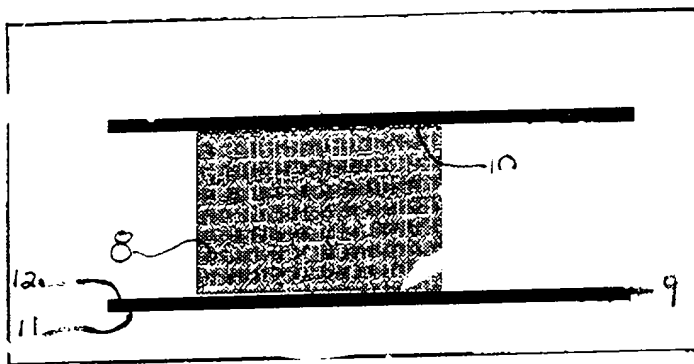


FIG. 3

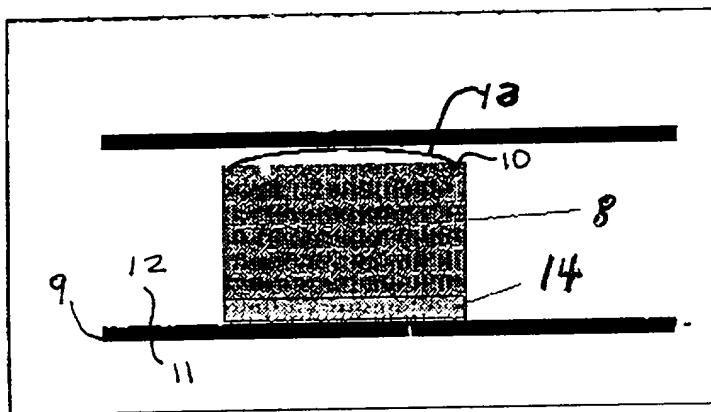


FIG. 4

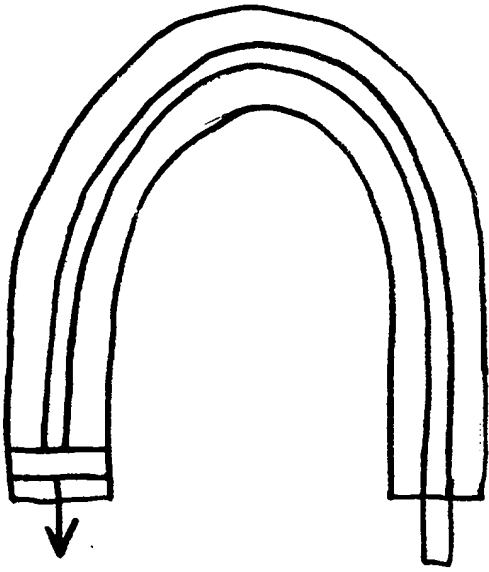


FIG. 5

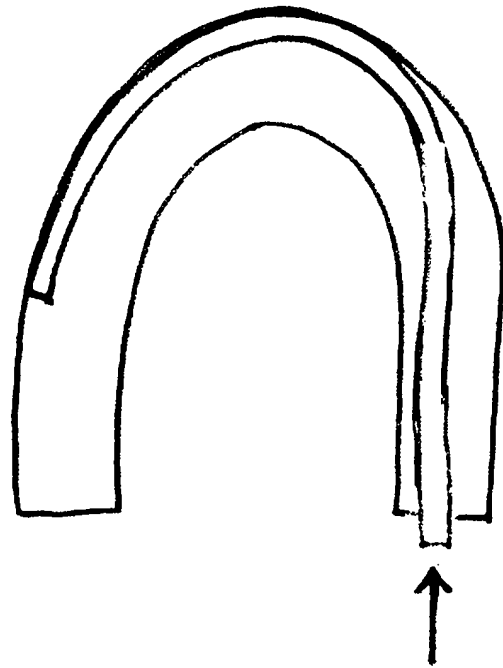


FIG. 6

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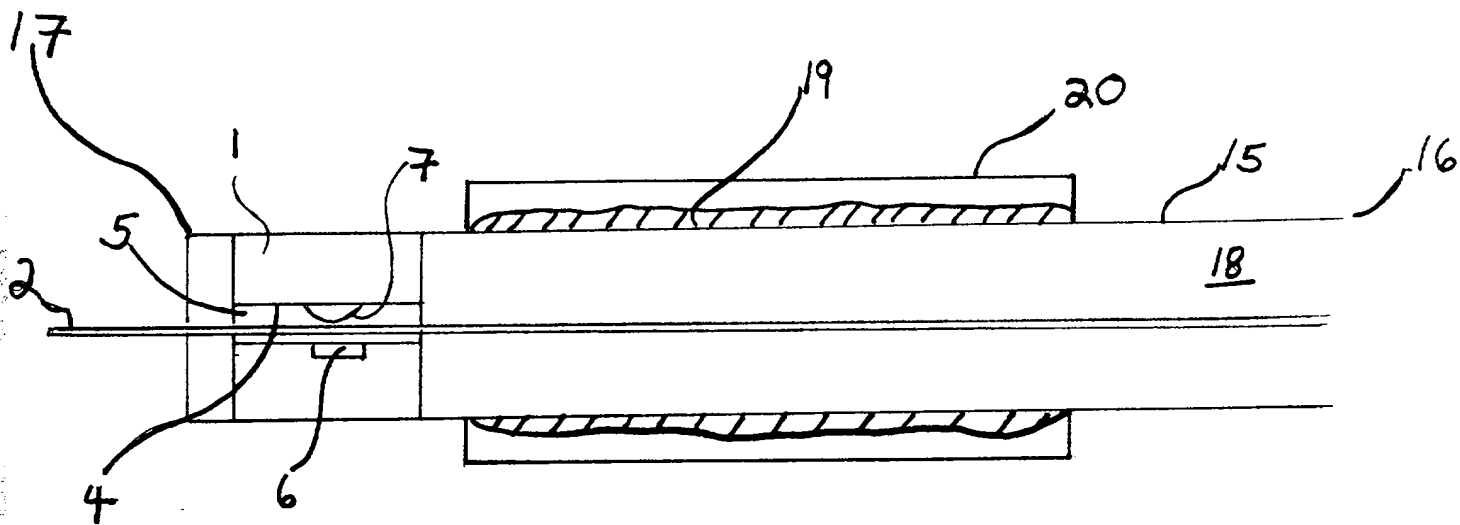


FIG. 7

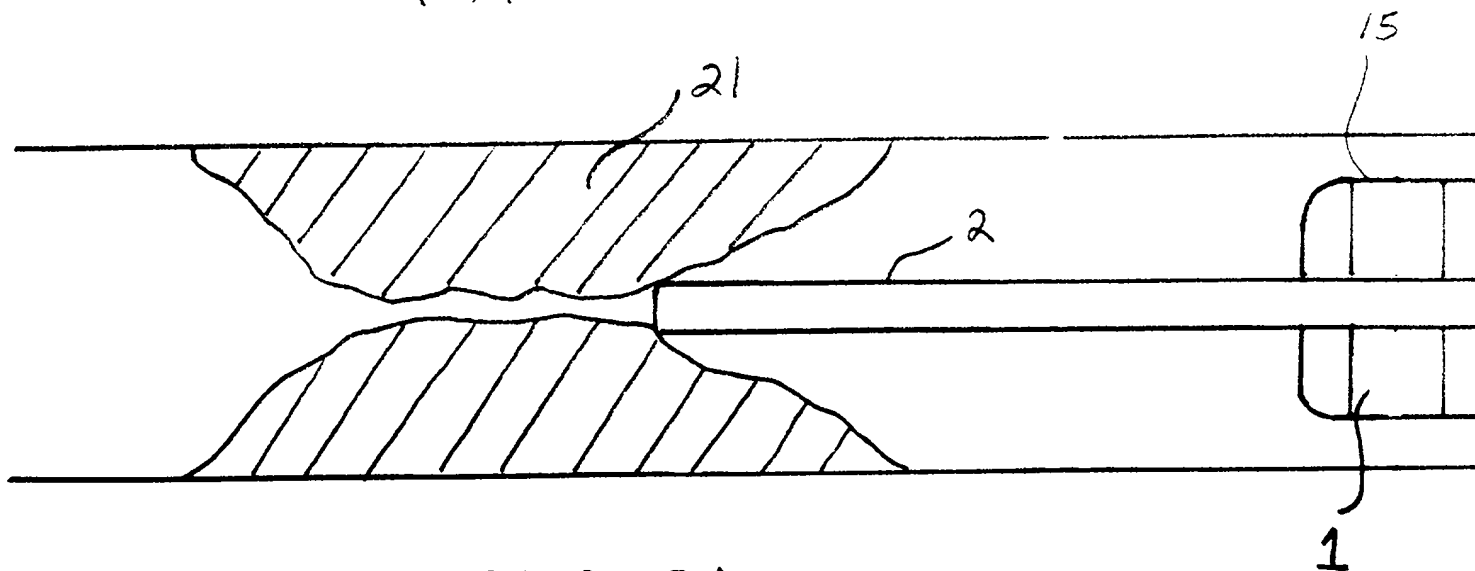


FIG. 8A

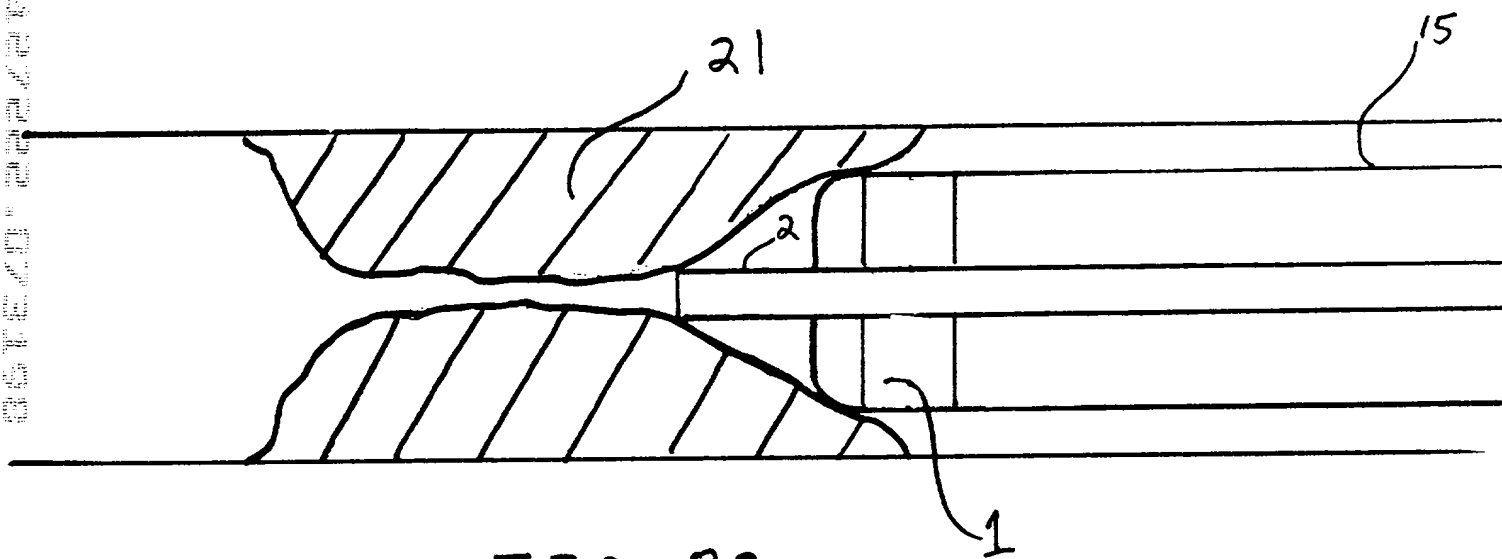
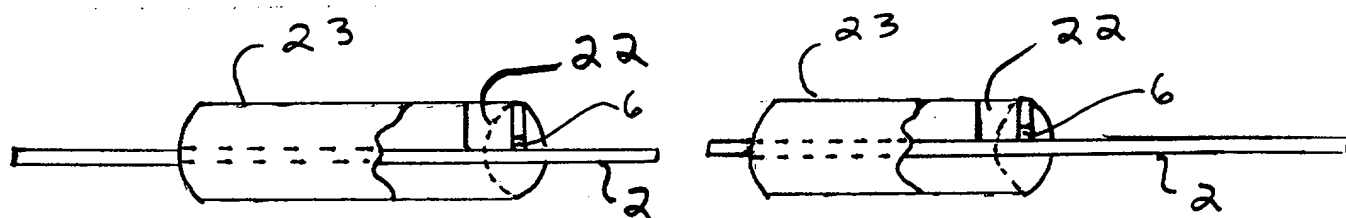
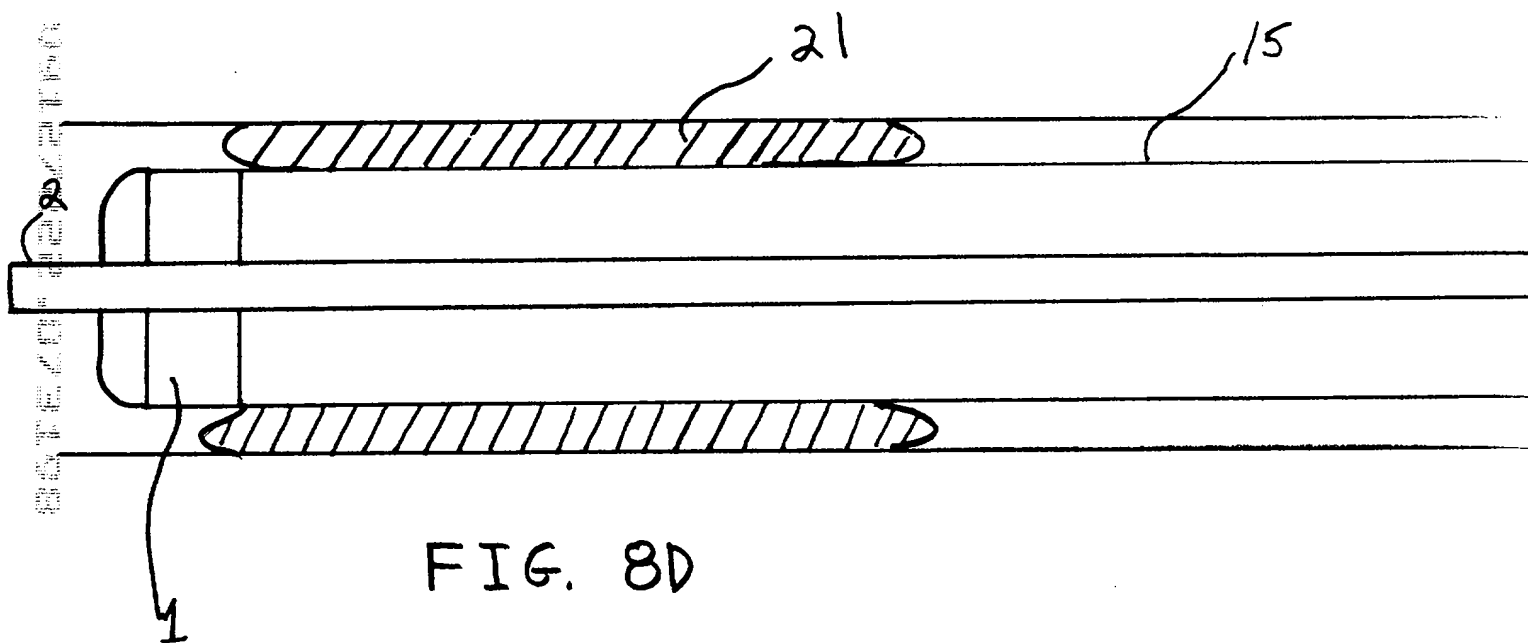
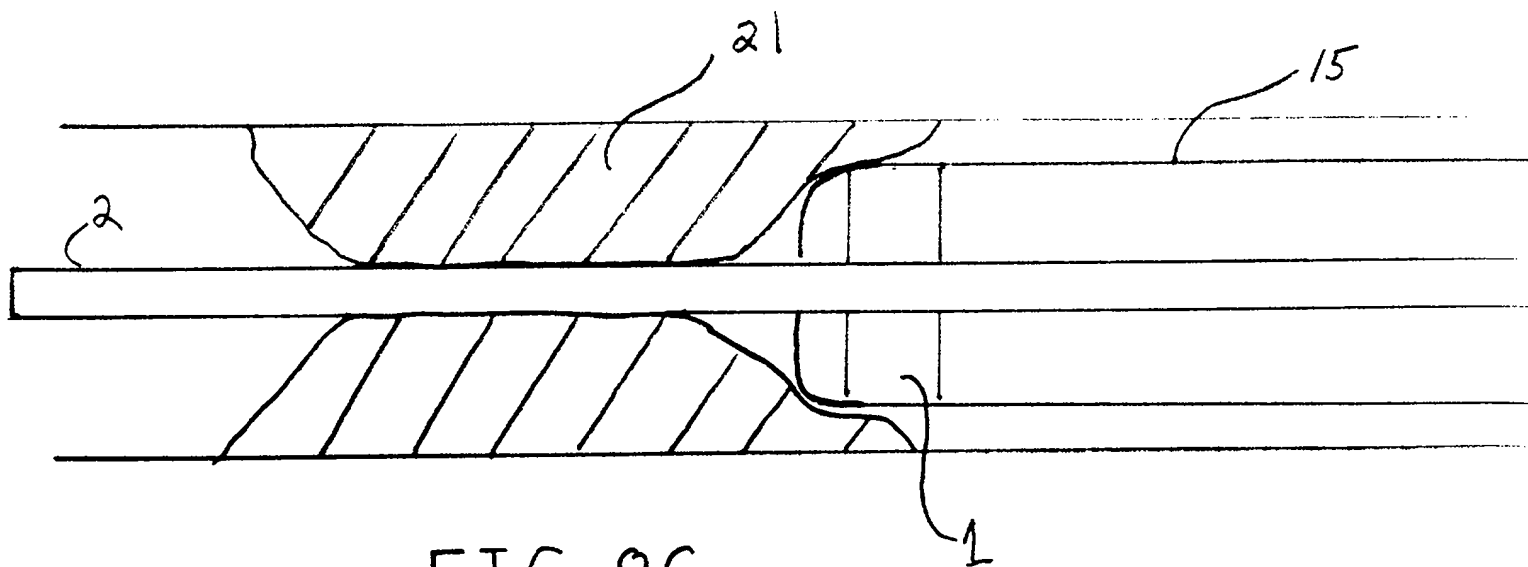


FIG. 8B



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DECLARATION AND POWER OF ATTORNEY

ATTORNEY'S DOCKET NO.
2600/47701

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name,

I believe I am an original, first, and joint inventor of the subject matter that is claimed and for which a patent is sought on the invention entitled **APPARATUS AND METHOD FOR SELECTIVELY POSITIONING A DEVICE AND MANIPULATING**, the specification of which is filed herewith.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a).

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorneys:

Charles R. Brainard (Reg. No. 21,069)
John E. Tsavaris, II (Reg. No. 33,804)

SEND CORRESPONDENCE, AND DIRECT TELEPHONE CALLS TO:

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I declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issuing thereon.

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